

REMARKS/ARGUMENTS

Claims 1, 5-10, 12, 15 and 18-29.

Claim 1 is amended to incorporate Claims 4, 11 and 13 and to define the elected subject matter. The non-elected subject matter has been cancelled. The remaining claim changes are for consistency with the amended claim 1.

Support for the amendment to claims 9-10 is found on page 15, last paragraph. The rejection applied to these claims under 35 USC 112, second paragraph is no longer applicable.

The specification is amended to make the noted correction regarding the trademark PLURONIC®. See page 15, last paragraph to page 16 for the generic terminology of this material.

No new matter is added.

The rejection of Claims 1-2, 6-13, 18-19 and 22-27 under 35 USC 102(b) citing WO 97/29767 to McNamara is not applicable to the claims because as correctly noted by not including Claim 4 (incorporated into Claim 1), McNamara does not describe compositions with sucrose. Withdrawal of the rejection is requested.

The rejection of Claims 1-2, 4-13, 18-24 and 26-29 under 35 USC 102(e) citing US 2006/0165733 to Betz is respectfully traversed.

Betz describes formulations with hGH and phenol (see para. [0039]). Betz mentions sucrose only in a long list of possible tonicity adjusting agents in paragraph [0042] but the preferred tonicity adjusting agent is mannitol (also described in the Examples). Citrate buffer is also mentioned as only one of several possibilities (see para. [0040]) selected between phosphate buffer, citrate buffer, acetate buffer and formate buffer with phosphate buffer not

citrate buffer as preferred (see Example 2 of Betz). While Applicants understand that a prior art disclosure is not limited to its preferred embodiments but rather all that it teaches, it is also the law that "It is not sufficient that each element be found somewhere in the reference, the elements must be 'arranged as in the claim.'" Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984). See also Ex parte Standish, 10 USPQ2d 1454, 1457 (Bd. Pat. App. & Int'l 1989) ("anticipation of a claimed product cannot be predicated on mere conjecture as to the characteristics of a prior art product").

In the case of Betz, the mere listing of two options is not considered to be sufficient to anticipate the claims because Betz simply does not arrange the mere suggested components in the manner that is claimed.

Accordingly, the Betz disclosure is not deemed to anticipate the claims as presented in this paper. Withdrawal of the rejection is requested.

The rejection of Claims 1, 2, 4-15 and 18-29 under 35 USC 103(a) based on Betz, US 5,567,677 to Castensson, and McNamara is respectfully traversed.

The deficiencies of Betz and McNamara as they relate to the present claims is discussed in detail above. Castensson is cited simply for the proposition that it would have been obvious to lower the pH of a liquid formulation of hGH to below 6.1 (see OA at page 5, item 11). In addition, to the comments above pertaining to McNamara it is also important to recognize that McNamara uses sugar alcohols such as mannitol as stabilizing excipient.

None of the above-referenced documents, either taken alone or in combination, renders the subject matter of the amended claim obvious. All three prior art documents disclose mannitol as a highly preferable tonicity adjusting agent. McNamara and Castensson

completely fail to disclose sucrose and thus cannot give the skilled person any motivation to use it in liquid formulations of growth hormone. Betz, the only document which makes a passing reference to sucrose, teaches that it is highly preferred to combine phosphate buffer and mannitol to obtain stable liquid formulations of growth hormone. The skilled person would be led away from using sucrose and even more so from combining it with citrate buffer for which there is no experimental basis.

Castensson cannot remedy this defect although it teaches that citrate is preferred over phosphate, since this document shows this preference only in the context of mannitol containing formulations which further fail to contain phenol.

Applicants understand that persons having ordinary skill in the art normally seek “to improve upon what is already generally known.” *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003). To establish that Applicants’ claimed process would have been obvious to a person having ordinary skill in the art, the prior art must reasonably suggest that persons having ordinary skill in the art do what Applicants claims require. Here, the only suggestion to do what Applicants have done is Applicants’ own disclosure, i.e. hindsight.

Where, as here, the rejection of the subject matter Applicants claim is based on hindsight, the rejection is improper. *In re Fritch*, 972 F.2d at 1266; *In re Fine*, 837 F.2d at 1075. Indeed, this must be true in light of the teachings of the references leading away from the specific combination of ingredients in the claimed formulation.

Reconsideration and withdrawal of the rejection is requested.

A Notice of Allowance is also requested.

Respectfully submitted,

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